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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/688,286	10/13/2000	TRACY WILLSON	11373A	3594

7590 10/31/2002

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EXAMINER
BASI, NIRMAL SINGH

ART UNIT	PAPER NUMBER
1646	12

DATE MAILED: 10/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 2/01)

Office Action Summary	Application No. 09/688,286	Applicant(s) Willson et al
	Examiner Nirmal S. Basi	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) X Responsive to communication(s) filed on *Jun 17, 2002* .

2a) This action is **FINAL**. 2b) X This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) X Claim(s) *16-19* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) X Claim(s) *16-19* is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) X The drawing(s) filed on *Oct 13, 2000* is/are a) accepted or b) X objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) X Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) X None of:

1. X Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____ .
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

2 Notice of Draftsperson's Patent Drawing Review (PTO-948) 4 Notice of Informal Patent Application (PTO-152)

3 Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 Other:

DETAILED ACTION

1. Response to Restriction filed 6/24/02 (paper number 11) and response to Notice to Comply under 37 CFR 1.821 (paper number 10) have been entered.

Election/Restriction

2. Applicant's election with traverse of Group IV, Claims 18 and 19, drawn to antibodies which bind recombinant polypeptide comprising SEQ ID NO:4, is acknowledged. The traversal is on the ground(s) that groups III and IV are not distinct but rather represent one single investitive concept warranting examination in a single application. This is not found persuasive because the inventions listed as Groups III and IV have distinct functional and physical properties capable of separate use and manufacture. A search of groups III and IV would not be co-extensive particularly with regard to the literature search. An examination of the materially different, patentably distinct inventions in a single application would constitute a serious undue burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

3. Acknowledgment is made of applicant's claim for foreign priority based on application filed in Australia on 10.23.95, 12.22.95 and 9.996 numbered PN-6135, PN-7276 and PO 2208

respectively. It is noted, however, that applicant has not filed a certified copy of applications PN-6135, PN-7276 and PO-2208 as required by 35 U.S.C. 119(b).

5. The drawings objected to because each Figure must described separately in the Brief Description of the Drawings. For example: a) Figure 1 should be labeled as Figure 1A, 1B, 1C, 1D, 1E and 1F and described in the Brief Description of the Drawings as Figure 1A-1F , or the equivalent, as required by 37 C.F.R. § 1.84 (u)(1). Similarly, Figures 3, 4, 5, 7 should be labeled and described accordingly.

6. The specification is objected to because the word following "is capable of" in claim 17, subsection (vi), is not legible. It appears the word may be "interaction" but it is not clear. Applicant is required to submit an amendment which clarifies the deficiency in claim 17 so that the examiner may make a proper comparison of the invention with the prior art.

7. ***Sequence Rules Compliance***

This application fails to comply with the sequence rules, 37 CFR 1.821-1.825. Nucleotide and polypeptide sequences must be identified with the corresponding SEQ ID NO. Title 37, Code of Federal Regulations, Section 1.821 states "reference must be made to the sequence by use of the assigned identifier", the identifier being SEQ ID NO. Sequences in Figures must be identified by their corresponding SEQ ID NO: and disclosed in the Brief Description of the

is not identified by SEQ ID NO:. Also application fails to comply with the Sequence Rules, 37 CFR 1.821 et seq., because claims 1 and 2 refer to an amino acid sequence without reference to a SEQ ID NO: identifier. Compliance with sequence rules is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

8. Claims 18 and 19 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 18 and 19 recite an antibody but does not recite that the antibody is isolated or purified. The claims as currently recited encompass naturally-occurring antibodies. Therefore, the compounds as claimed are a product that occurs in nature and does not show the hand of man, and as such is non-statutory subject matter. It is suggested that the claims be amended to recite "an isolated and purified" to overcome this rejection.

Claim Rejection, 35 U.S.C. 112, second paragraph

9. Claims 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards

Claims 18 and 19 are indefinite because it is not clear what is, "An antibody to the recombinant polypeptide of according to claim 16 and 17" and what is "An antibody according to claim 16 wherein said antibody is a monoclonal antibody", so as to allow the metes and bounds of the claim to be determined. It is not clear if the antibody binds to the polypeptide of claims 16 and 17. Further in claim 19, the statement "an antibody according to claim 16" is not clear. Claim 16 is drawn to a polypeptide not an antibody.

Claim Rejection, 35 U.S.C. 112, first paragraph

10. Claims 18 and 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody which specifically binds the polypeptide consisting of SEQ ID NO:4 or the polypeptide encoded by the polynucleotide of SEQ ID NO:3, does not reasonably provide enablement for the scope of other antibodies. Specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification discloses the polypeptide of SEQ ID NO:4 and the polynucleotide of SEQ ID NO:3. Antibodies can be generated to many epitopes found in the polypeptide of SEQ ID NO:4. Due to the comprising language, the claims encompass antibodies which bind to polypeptides which may be unrelated, structurally and functionally to the polypeptide of SEQ ID NO:4.. The claims as written do not specifically require that the antibodies bind to protein of SEQ ID NO:4 or to even active proteins. The specification does not teach how to use a commensurate number of antibodies

The claims as written do not specifically require that the antibodies bind to protein of SEQ ID NO:4.

Further the claims are similar to single means claims in that claims recite any antibody that binds a polypeptide having two or three of the characteristics disclosed in claims 16 and 17, but the specification only discloses molecules of SEQ ID NO:4. MPEP 2164.08(a) defines a single means claim as a claim which covered every conceivable means for achieving the stated purpose when the specification disclosed at most only those means known to the inventor. This type of claim was held to be nonenabling for the scope of the claim in In re Hyatt, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983) because the specification disclosed at most only those means known to the inventor. When claims depend on a recited property (i.e. antibody binding a protein defined only by function and without a defined amino acid structure) , a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. This appears to be the instant case and the claims are not commensurate in scope with the specification.

While the person of ordinary skill in the art, would, in light of the specification, be able to make antibodies which specifically bind the polypeptide of SEQ ID NO: 4, the scope of the claims, which encompass antibodies binding to any polypeptide stated as having as at least two or three of the characteristics disclosed in claims 16 and 17, which encompass mutants and proteins unrelated to the polypeptide of SEQ ID NO:4 , is simply not enabled by the disclosure. For example, an

ID NO:4, wherein said the polypeptide is encodes by a nucleotide substantially as set forth in SEQ ID NO:3 and interacts with a derivative of IL-13 may be completely unrelated to antibodies which specifically bind to the polypeptide of SEQ ID NO:4. Said "unrelated antibodies" encompass antibodies which do not bind specifically to the polypeptide of SEQ ID NO:4, since they may bind only to the polynucleotide sequence that is 50% different to that contained in SEQ ID NO:4, or which may bind to fusion products not contained in SEQ ID NO:4. The disclosure does not teach how make and use many of the numerous antibodies which are capable of binding polypeptides which did not contain an epitope specific for the polypeptide of SEQ ID NO:4.

Instant claim also fails to identify the antibody in terms of its specific structure or in terms of the specific structure it binds but only that it binds a genus of polypeptides without a specific defined structure containing millions of possible variants. Apart from the antibodies that bind specifically to the polypeptide of SEQ ID NO:4 there is no disclosure of the antibodies which would bind the mutants and variants encompassed by the claims. The variants of the proteins bound by the claimed antibody may not contain many of the features of the protein of SEQ ID NO:4. The claim also encompasses all possible mutations and deletions of the protein. Although the skilled artisan can produce nucleic acid variants and mutants encoding the polypeptide of SEQ ID NO:4, due to the large amount of experimentation necessary to test variants and mutants within the scope of the claimed antibody and to determine how antibodies that bound to variants and mutants which were inactive, or bound to unrelated polypeptides, the lack of guidance presented in the specification

invention, the state of the prior art in the unpredictability of protein folding, and the breadth of the claims which fail to recite structural limitations, undue experimentation would be required of the skilled artisan to make and use the claimed invention in its full scope.

Further instant fact pattern closely resembles that in Ex parte Maizel, 27 USPQ2d 1662 (BPAI 1992). In Ex parte Maizel, the claimed invention was directed to compounds which were defined in terms of function rather than sequence (i.e., "biologically functional equivalents"). The only disclosed compound in both the instant case and in Ex parte Maizel was the full length, naturally occurring protein. The Board found that there was no reasonable correlation between the scope of exclusive right desired by Appellant and the scope of enablement set forth in the patent application. Even though Appellant in Ex parte Maizel urged that the biologically functional equivalents would consist of proteins having amino acid substitutions wherein the substituted amino acids have similar hydrophobicity and charge characteristics such that the substitutions are "conservative" and do not modify the basic functional equivalents of the protein, the Board found that the specification did not support such a definition, and that the claims encompassed an unduly broad number of compounds. Such is the instant situation. Clearly, a disclosed sequence of SEQ ID NO:4 does not support claims to any antibody binding to any polypeptide having at least two or three characteristics disclosed in claims 16 and 17, given the lack of guidance regarding what antibodies would bind polypeptide of SEQ ID NO:4 and and not other, related sequences.

In conclusion, the claims encompasses antibodies which bind to polypeptides comprising

which may be completely unrelated, structurally and functionally to the polypeptide of SEQ ID NO:4. As pertaining to the scope of variants claimed, without a disclosure of the critical feature required for activity and specific mutations which can be produced which retain said activity, antibodies which bind variants encompassed by the claims are not enabled by the disclosure. The polypeptides which are variants may be functionally and structurally unrelated to the SEQ ID NO:4. There is no disclosure on how to assay for said protein or how to use a commensurate number of said proteins, some of which may be inactive. The instant specification fails to provide any descriptive information on "variants", such as definitive structural features and their relationship to function. There is no description, however, of the sites at which variability may be tolerated, which amino acids are to be substituted to produce "variants" with a disclosed function. Structural features that could distinguish the compounds in the genus from others are missing from the disclosure. There is no disclosure of the critical technical feature of the invention. Many of the variants, mutants and fragments encompassed by the scope of the claims will be inactive or have activities unrelated to the protein of SEQ ID NO:4. The specification does not teach how to make antibodies to functional/non functional variants and mutants encompassed by the claims or to use inactive variants. The prior art teaches that amino acid substitutions produce unpredictable results in a structurally related protein. Furthermore, neither the specification nor the prior art provide any guidance as to which amino acids could be altered, nor does the specification provide any guidance as to how the skilled artisan could use an inactive variants, mutants. Therefore, it would require

no reasonable expectation that variants and mutants could be used for any purpose. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to make, isolate, identify and use the claimed antibody variants encompassed by the claims without undue experimentation.

Therefore, due to the lack of direction/guidance presented in the specification regarding the production, identification, purification, isolation and characterization of the mutants and variants, encompassed by the claims, the unpredictability of the effects of mutation on the structure and function of proteins, and the breadth of the claim which fail to recite specific structural and functional limitations, undue experimentation would be required of the skilled artisan to make or use the claimed invention in its full scope.

11. Claim 18 and 19 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

The claims are drawn to antibody which binds a polypeptide having at least two or three of the characteristics disclosed in claims 16 and 17.

The specification discloses a distinct polypeptide consisting of SEQ ID NO: 1. The instant

antibodies, which bind a substantial variety of subgenera including full-length, truncated, fusion polypeptides and variants thereof. The claims encompass antibodies which may not even bind to the polypeptide of SEQ ID NO:4. A description of a genus antibodies may be achieved by means of a recitation of a representative number of polypeptides they bind, defined by an amino acid sequence, falling within the scope of the genus and a recitation of structural and functional features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural and functional features of the claimed genus of antibodies. There is no description of the conserved regions which are critical to the structure and function of the polypeptide of SEQ ID NO:2. There is no description of the critical feature of the invention, the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the antibodies encompassed and no identifying characteristic or property of the instant polypeptides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

The specification further fails to identify and describe the regulatory regions essential to the

encompasses the antibodies that bind full length, truncated, fusion polypeptides and variants thereof.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of the ability to produce antibody and the ability to screen, is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

An adequate written description of a protein, requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention. Accordingly, an adequate written description of a protein is more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the protein itself. Accordingly, the specification does not provide a written description of the invention of claim 18 and 19.

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this

[illegible] should be directed to [illegible]

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi
Art Unit 1646
October 21, 2002